Schweizerische Eidgenossenschaft
Confédération suisse
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Federal Department of Economic Affairs,
Education and Research EAER

Agroscope

Development of a framework for the evaluation and prioritization of food and feed safety hazards and related research needs

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Aims

- Prioritization of the different classes of hazards: (micro-) biological, chemical, physical, and nutritional, in foods and feeds
- Prioritization of related research needs
- Simple, fast and easy to use - Tool
- No need to perform complete scientific risk assessment
- Include typical local and national conditions

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Problems

- Chemical risks have acute and long term end points
- (Micro-) biological risk estimates concerning illnesses and deaths differ widely
- Comparison of (micro-)biological and chemical risks
- Widely differing estimates for deficient or excessive food intake and imbalanced diet

Proceeding

- Prioritizations are applied to triplets formed by:

  Product matrix (food or feed), its processing (with possible change of hazard), the respective hazard

- A basis of measurable descriptors was found either as:

  DALYs (Disability Adjusted Life Years)

  or

  Illness and death cases in a population, respectively the Economic cost estimates resulting thereof

Proceeding

DALY ist eine Abkürzung aus dem Englischen mit der Bedeutung disability-adjusted life years oder auch disease-adjusted life years (lost).

Mit DALY soll nicht nur die Sterblichkeit, sondern auch die Beeinträchtigung des normalen, beschwerdefreien Lebens durch eine Krankheit erfasst werden und in einer Maßzahl zusammengerechnet werden.

Es misst Gesundheitslücken und „beschreibt den Unterschied zwischen einer tatsächlichen Situation und einer idealen Situation, in der jede Person bei voller Gesundheit bis zu dem Alter lebt, das den Standardwerten der Lebenserwartung entspricht“.

Definition nach Global Burden of Disease Bericht der WHO, 2011

Literature (measurable descriptors):

- van Kreijl C.F., Knaap A.G.A.C. and Raaij J.M.A. (Editors-in-Chief). Our food, our health. Healthy diet and safe food in the Netherlands. rivm (national institute for public health and the environment). RIVM report number 270555009, ISBN 90-6960-135-4, ISBN 978-90-6960-135-9, NUR 882. 2006
  (available at http://www.rivm.nl/bibliotheek/rapporten/270555009.pdf).
- Siebert. B.D. Natural chemicals and food safety. CSIRO Division of Human Nutrition at the regional Institute Inc., Australia, Glenthorne Laboratory. O'Halloran Hill, SA 5158. 1992
  (available at http://www.regional.org.au/au/roc/1992/roc1992055.htm) .
- Mead P.S. et al. Food-Related Illness and Death in the United States. Emerging Infectious Diseases Vol. 5, No. 5, 1999
  (available at http://www.cdc.gov/ncidod/eid/Vol5no5/mead.htm).

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Relevance for human health- by far the most important criterion

- The incidence and severity of adverse health effects must show up within the “relevance for human health”- criteria

Hazard	**Netherlands, DALYs based factors**	**USA/Australia, Fatalities/costs based factors**
Unfavorable dietary composition and overweight	1	1
(micro-) biological agents	0.0025 – 0.01	0.05 - 0.3
Chemical contamination: pesticides, naturally occurring chemical compounds, toxins or contaminants including allergens	0.00375 – 0.005	
Allergens alone	0.0025	
Environmental chemicals or natural toxicants	0.00125 – 0.0025	0.001
Pesticide residues or food additives		0.00001

Table 1: Criterion *Relevance for human health* of different food borne hazards at the example of the Netherlands (based on DALYs) and the Example of USA and Australia (based on fatalities and costs).

User friendly tool-interface

1 Human Health & 6 Exposure Criteria

Other Legitimate Criteria: relevant for value chain

Product x Hazard x Processing = FLEXIBILITY

Date	21.01.2013		
Assessor	mum		
Product	Raw milk		
Contaminant	EHEC 0157		
Intended use / processing	Production of raw milk cheese		
Factor		**Weighting**	
Quality of agent	microbiological		
Agent impact on human health	Microbial contaminants	0.01	
Dissemination of hazard / biological and chemical agents	high impact (virulence or infectivity) in human and animal	5	
Entry to food chain	farm & processing	2	
Importance of food / feed ingestion	normal food/feed, weekly to monthly consumption	2	low infection dose
Changes due to food processing	basic food/feed, daily to weekly consumption normal food/feed, weekly to monthly consumption speciality, monthly to yearly consumption	0.1	
Expansion of hazard / risk	international (import / export)	3	substantial amount exported
Regulatory concern and internal status	ongoing (inter-) national cooperation	3	
		0.18	
ther legitimate criteria			
media interest (extrapolation)	medium, normal information	2	no cases of illness known
consumer control of hazard	no	3	
familiarity of specalists with hazard	basic knowledge, medium need for research	2	research needed for optimisation of production process
affected groups of population	all, entire population	3	
		36	
	Total priority points TPP	**6.48**	Rating transfer in data base

Scientific criteria (I)

Impact on human health spreads the different hazards up to ten-thousand fold

The other scientific criteria together modulate from a minimal reduction factor of 0.1 to a maximal multiplication factor of 3240.

Factor
Quality of agent
Agent impact on human health
Dissemination of hazard / biological and chemical agents
Entry to food chain
Importance of food / feed ingestion
Changes due to food processing
Spread of hazard / risk
Regulatory control options

- Quality of agent:

Defines if the hazard is of chemical, microbiological, physical or nutritional nature, then selects the appropriate sets of sub-criteria for the selected type of hazard.

- Dissemination:

describes the agent`s capacity of reaching living beings (humans, animals).

Explanation (Exposition)

Factor
Quality of agent
Agent impact on human health
Dissemination of hazard / biological and chemical agents
Entry to food chain
Importance of food / feed ingestion
Changes due to food processing
Spread of hazard / risk
Regulatory control options

- Entry to the food chain:

  assumes contaminations to be more hazardous when present in the food or feed near consumption because there remains less possibility for its detection and minimization.
- Importance of food or feed ingestion: associates the probability of ingestion with the ingested amount.
- Changes due to food processing: informs about the amount of hazard expected in the final product.
- Spread of the hazard: defines the area of influence (local, national, import/export).
- known and regulated (and controlled) hazards: imply a reduction of hazards present in foods and feeds towards acceptable levels.

Criteria related to the perception of risk

- The 4 criteria related to the perception of risk modulate a maximal multiplication factor of 72

Criterion	Sub-criteria
Media interest (extrapolation)	Headline coverage (i.e. due to fraud, political debate, scandal)
	Little or medium coverage
	No coverage
Consumer control over hazard	no
	yes
Data gaps	No knowledge and high research need
	Basic knowledge and medium research need
	Good knowledge and no research need
Affected persons	General population
	Subpopulations (YOPI)*
	Sensitive individuals

Thus, the factors separating the principal categories of food hazards may be passed or changed.

Explanation (other legitimate criteria)

Other legitimate criteria
media interest (extrapolation)
consumer control over hazard
data gaps (familiarity of specalists with hazard)
affected persons

- Perception of risk depend on:

individual risk estimations and evaluations

- Media coverage:

appreciation when trying to avoid scandals e.g. due to fraud or insufficient controls and when trying to avoid loss of trust

- Consumers may show increased risk tolerance:

when they exert personal control over a risk, when the risk is voluntarily taken, when it is familiar or when there exists institutional control by a confident institution

- It is important, how many and what persons are affected: i.e. appealing persons like children or mothers (Lit:Renn,O.Univ.Stuttgart,2008)

Examples: microbiological agent (I)

Date	21.01.2013		
Assessor	mum		
Product	Raw milk		
Contaminant	EHEC 0157		
Intended use / processing	Production of raw milk cheese		
		Clear contents	
Factor		**Weighting**	**Comments, remarks**
Quality of agent	microbiological		
Agent impact on human health	Microbial contaminants	0.01	
Dissemination of hazard / biological and chemical agents	high impact (virulence or infectivity) in human and animal	5	
Entry to food chain	farm & processing	2	
Importance of food / feed ingestion	normal food/feed, weekly to monthly consumption	2	low infection dose
Changes due to food processing	basic food/feed, daily to weekly consumption normal food/feed, weekly to monthly consumption speciality, monthly to yearly consumption	0.1	
Expansion of hazard / risk	international (import / export)	3	substantial amount exported
Regulatory concern and internal status	ongoing (inter-) national cooperation	3	
		0.18	
Other legitimate criteria			
media interest (extrapolation)	medium, normal information	2	no cases of illness known
consumer control of hazard	no	3	
familiarity of specalists with hazard	basic knowledge, medium need for research	2	research needed for optimisation of production process
affected groups of population	all, entire population	3	
		36	
	Total priority points TPP	**6.48**	Rating transfer in data base

Listing and ranking of input sets

For final rating, sub-criteria are given a numerical value according to the respective importance. These values are multiplied to the final rating value, which is automatically classified by colors:

Ranking	TPP	scientific factor	Factor "Other legitimate criteria"	Product	Contaminant	Intended use / processing	Assessor	Date of ranking
3	4.320	0.2400	18	Flour	Aflatoxin B1	Production of bread	test	16.07.2012
1	6.480	0.1800	36	Raw milk	EHEC 0157	Production of raw milk cheese	mum	21.01.2013
2	5.830	0.2160	27	Milk	Aflatoxin M1	Production of cheese	BLK	04.02.2013

- Data records are automatically ranked after insertion into data base
- Optical discrimination of ranking by color gradient
- Indicator function for fraud

Weitere Arbeiten und Entwicklungen

Das aktuelle Tool genügt für die Evaluation von Forschungsprioritäten.

- Validierung des Systems durch Bewertung diverser Kontaminationen von Personen aus verschiedenen Berufsgruppen. Daraus ergeben sich Aussagen über die Verlässlichkeit der Priorisierungen.
- Mit dem Durchspielen möglicher Szenarien können die risikoreichsten Kombinationen ermittelt werden.

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Weitere Arbeiten und Entwicklungen

- Die ADK vom 12.11.2013 akzeptiert die Ausarbeitung eines Priorisierungstools für Produktekontrolle unter Einbezug aller betroffenen Akteure

- Die Konferenz Lebensmittelkette KLMK, bestehend aus VertreterInnen der kantonalen Laboratorien und von BLW/BAG/BVET/BLK informiert und beschliesst am 3.12.2013:

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Weitere Arbeiten und Entwicklungen

Konferenz Lebensmittelkette KLMK vom 03.12.2013:

«Eine …Mitarbeit der kantonalen Behörden bei der Entwicklung eines … PrioTools ist sehr wichtig, um ihr Expertenwissen …zu integrieren und … die Praxis-tauglichkeit und Bedienerfreundlichkeit …für den kantonalen Kontext gewährleisten zu können.

Die … Entwicklung des PrioTools wird es ermöglichen, eine wissenschaftlich fundierte Methode gemeinsam in ein PrioTool zu implementieren, welches den Bedürf-nissen der einzelnen Behörden entsprechend individuell angewendet werden kann.»

➔ **ROUND TABLE**

PD Dr. Philipp Hübner, Vorschlag 1

Kantonschemiker Basel

Der Vollzug der eidgenössischen Lebensmittelgesetzgebung bezieht mit ein:

- Schutz vor Gesundheitsgefährdung
- den hygienischen Umgang mit Lebensmitteln
- Den Schutz vor Täuschung
- die sachkundige Wahl

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Vorschlag 2

Erstellung der Liste der relevanten Risiken
mit Hilfe folgender Daten:

- Beanstandungen in den Kantonalen Laboratorien 2012
- RASFF Alerts 2003 bis 2012
  Rapid Alert System of Food and Feedstuff der EU
- RAPEX Meldungen 2011 (teilw.) und 2012
  Rapid Exchange of Information System, Schnellwarnsystem der EU für den Verbraucherschutz.

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Vorschlag 3

- Hauptindikator für die Risikoabschätzung ist das DALY Konzept (disability adjusted life years)
- Mit dem DALY-Konzept soll die Bedeutung verschiedener Krankheiten auf die Gesellschaft gemessen werden.
  DALY erfasst nicht nur die Sterblichkeit, sondern auch die Beeinträchtigung des normalen, beschwerdefreien Lebens durch eine Krankheit.
- (http://de.wikipedia.org/wiki/DALY)

Vorschlag 4

Risiko ist definiert als

- das mathematische Produkt von Gefährdungspotential (Gefahren) und
- der Eintretenswahrscheinlichkeit.

Risiko =
DALY x (Exposition x % Beanstandungen in KL)

Andere Ansätze

FDA-iRISK version 1.0 (available at http://irisk.foodrisk.org/)
Food and Drug Administration Center for Food Safety and Applied Nutrition (FDA/CFSAN), Joint Institute for Food Safety and Applied Nutrition (JIFSAN) and Risk Sciences International (RSI). FDA CFSAN.

Modell ETHZ – BAG:
Prioritization for Risk Management of Foodborne Hazards (http://www.toxicology.ethz.ch/research/topics/Project_5)

Institute of Food, Nutrition and Health ETH Zurich Schmelzbergstrasse 9, LFO D25
8092 Zurich, Switzerland

(Beispiel für praktische Anwendung in Lebensmittel-Technologie 10/13, p. 10-11)

Vorteile des einfachen Ansatzes

“Die Erfahrungen zeigen, dass sich nur einfach umzusetzende Bewertungsmethoden für eine Standardanwendung in der regulatorischen Praxis eignen. … Modelle, die umfangreiche toxikologische Informationen und bezüglich der Exposition die Handhabung großer Datenbestände und komplexer probabilistischer Rechenmodelle verlangen, sind dafür untauglich.”

BfR Deutschland: Cumulative pesticide residues in food should be assessed on the basis of clear and simple criteria. WFRR Vol. 22 Nr. 12, pp. 9-10, May 2013.

Das Agroscope-Modell ist kompatibel mit dem Modellansatz des CODEX-Alimentarius

Wie weiter?

- Validierung der Beurteilungen durch Fachpersonen
- Ermitteln der risikoreichsten Kombinationen (worst case scenarios)
- Einarbeitung der Vorschläge von Seiten der Kantonalen Laboratorien
- Weiterentwicklung und Spezifizierung auf die Bedürfnisse über den Runden Tisch innerhalb der KLMK
- Weiterentwicklung und Spezifizierung auf die Bedürfnisse von Lebensmittel verarbeitenden Betrieben

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